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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,198	02/01/2002	Avi J. Ashkenazi	P3130R1C6	6051

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EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/066,198

Applicant(s)

ASHKENAZI ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 40-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/29/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED OFFICE ACTION

Applicant's preliminary amendment filed on 01 February 2002 is acknowledged and entered. Following the amendment, the original claims 1-39 are canceled, and the new claims 40-45 are added.

Currently, claims 40-45 are pending and under consideration.

#### **Formal Matters:**

##### ***Priority***

This application claims priority to US provisional application 60/149,396, PCT/US00/08439, PCT/US00/13358, PCT/US00/14042, and US application 10/002,796. For the following reasons, the Examiner finds that the present claims 40-52 are not supported in the manner required by 35 U.S.C. 101 and 112, first paragraph by the prior applications, thus none of present claims is entitled to the benefit of the filing date of the prior applications.

The priority documents 60/149,396, PCT/US00/08439, PCT/US00/13358 merely disclose a polynucleotide sequence of SEQ ID NO:62 encoding a polypeptide of SEQ ID NO:63, which is designated PRO7170, and they fail to provide any specific, substantial and credible utility, nor guidance or working examples to teach how to use the claimed invention. The later PCT/US00/14042, and US application 10/002,796 disclose a working example (Example 61) indicating that the PRO7170 polypeptide was tested positive as either stimulators or inhibitors of glucose or FFA uptake in skeletal muscle, which is determined as insufficient to support a specific and substantial utility for the reasons addressed under **Objections and Rejections under 35 U.S.C. §101 and §112** below. Therefore, the Examiner is not able to establish that any of the priority documents satisfies the utility/enablement requirement of 35 U.S.C. 101/112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of above prior applications, and the effective filing date for the instantly claimed invention is 02 February 2002, the actual filing date of the instant application.

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***Title***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

**Objections and Rejections under 35 U.S.C. §101 and §112:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 40 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 40, as written, does not sufficiently distinguish over antibodies as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”. See MPEP 2105.

Claims 40-45 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility.

Claims 40-45 are directed to an antibody that binds to the polypeptide of SEQ ID NO:63, which is designated PRO7170.

The specification discloses a human polypeptide, PRO7170, having an amino acid sequence SEQ ID NO:63, and an antibody thereto. The specification does not disclose any specific biological significance directly associated with the PRO7170. A working example of detection of polypeptides that affect glucose or FFA uptake in skeletal muscle (Example 61) is noted in the specification, in which PRO7170 polypeptide, along with several other polypeptides, were tested positive as *either stimulators or inhibitors* of glucose or FFA uptake (page 143, lines 12-14). Such cannot be used to support a specific and substantial utility for the PRO7170 because the specification does not make it clear whether the PRO7170 stimulates

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or inhibits glucose or FFA uptake as stimulation and inhibition are mutually exclusive, and both cannot be true. Further, even if the PRO7170 were specifically indicated to stimulate or inhibit glucose or FFA uptake in skeletal muscle, it does not constitute an assertion of a specific and substantial utility because it is still unclear whether such an activity is associated with any biological significance, what it can be used for in a "real world", and what well-established utility is associated with the activity. As such, the antibody to the PRO7170 polypeptide does not have a specific and substantial, or well-established utility.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-45 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite for the recitation of "the antibody ... is an antibody fragment" as an antibody cannot be an antibody fragment in the same time.

Claim 45 is indefinite for the recitation of "specifically binds" because it is not defined in the specification; one of skill in the art would not know what the metes and bounds of "specifically" were intended to be and would not know what level of binding, and thus what antibodies, were included in the limitations of the claims. Further, it is unclear how the term "specifically binds" differs from "binds" in claim 40.

**Rejections Over Prior Art:**

**The following rejections under 35 U.S.C. §§ 102 and 103 are made in view of the determination that the effective filing date for the instantly claimed invention is 02 February 2002, which is the actual filing date of the instant application.**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bandman et al. (WO 00/68380).

Bandman disclose a human polypeptide sequence, EXMAD-3 (SEQ ID NO:3), which is an extracellular matrix and adhesion-associated protein, and is 100% identical to SEQ ID NO:63 of the instant application (see computer printout of the search results). Further, Bandman teaches an antibody binding to said polypeptide or a fragment thereof (page 9, lines 26-32), including monoclonal antibody, antibody fragments (page 37, line 34 to page 38, line 2), humanized antibody (page 38, lines 24-26), and labeled antibody (page 45, lines 4-8). As such, the reference anticipates the present claims 40-45.

**Conclusion:**

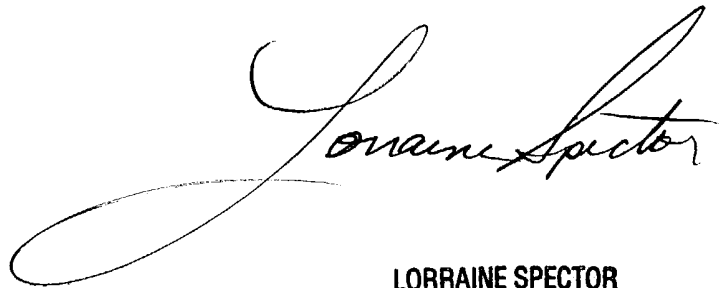
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in black ink, reading "Lorraine Spector". The signature is written in a cursive style with a large, looping initial "L".

**LORRAINE SPECTOR  
PRIMARY EXAMINER**

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
6/8/04